IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE FACTOR VIII OR IX CONCENTRATE BLOOD PRODUCTS LITIGATION JAMES LANDMESSER, JR., a resident of Silver Spring, Maryland, Plaintiffs, v. BAYER CORPORATION, an Indiana corporation, successor to CUTTER BIOLOGICAL, a California Corporation; BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and its HYLAND DIVISION; ARMOUR PHARMACEUTICAL COMPANY, INC., a Delaware corporation; and ALPHA THERAPEUTIC CORPORATION, a California corporation, Defendants.	**MDL NO. 986 JFG** **NO. 1:93cv7452** **THIS DOCUMENT RELATES TO:** **The Action Listed Below** **CASE NO. 1:08-cv-03872** **E-FILED** **ANSWER OF DEFENDANT BAYER CORPORATION TO COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF** **JURY DEMAND** **DISCLOSURE STATEMENT**

Defendant BAYER CORPORATION (hereinafter referred to as "Bayer") objects to Plaintiff's Complaint on the ground that this Complaint is not the short and plain statement of a claim required by Rule 8 of the Federal Rules of Civil Procedure. Many of the allegations are argumentative, vague, ambiguous and therefore objectionable, including, but not limited to, all allegations said to have occurred "at all pertinent times" which is not otherwise defined. Much of the Complaint consists of quotations from newspapers and other publications and documents.

Bayer objects to having to guess at what allegations against Bayer, if any, Plaintiff is making by quoting what others have written.

Without waiving any of the foregoing objections, even if not specifically repeated hereafter, defendant Bayer, in response to Plaintiff's Complaint on file, answers each and every cause of action allegedly set forth therein, and admits, denies, and alleges as follows:

I. ANSWER TO PLAINTIFF'S INTRODUCTION

1. Defendants manufactured blood products known as "Factor VIII" and "Factor IX" for the treatment of hemophilia, and sold these products to people with hemophilia in the United States and worldwide, despite knowledge that the products were manufactured from sick, high-risk donors and/or known to be contaminated with the virus that causes Non-A, Non-B Hepatitis (now known as "Hepatitis C" or "HCV"). Defendants knowingly declined to timely pursue or adopt treatment and manufacturing practices that would have prevented the infection of Plaintiff with HCV, as described in more detail below. Defendants also continued selling old stocks of products they knew to be contaminated with HCV even after they or others had introduced safer products. Plaintiff is a person with hemophilia who contracted HCV through use of Defendants' contaminated products. This complaint describes the factual predicate for Plaintiff's infection: a pattern of foot-dragging, denial, and obfuscation by the pharmaceutical companies on whom his health and well-being depended.

First Defense

PARAGRAPH NO. 1 ANSWER: In response to the allegations in Paragraph 1 of the Complaint, Bayer admits that, beginning in 1968, it or one of its predecessors was licensed by the Food and Drug Administration ("FDA") to process and distribute Factor IX, and that, beginning in 1974, it or one of its predecessors was licensed by the FDA to process and

distribute Factor VIII. Bayer further admits that treatment of hemophilia includes intravenous introduction of missing blood components essential for coagulation and that prevalent forms of such treatment include blood factor concentrates containing Factor VIII and Factor IX. Bayer further admits that it engaged in the collection of plasma and the processing and distribution of Factor VIII and Factor IX produced from such plasma and that Bayer processed plasma taken from human donors. Bayer denies all allegations in this and numerous subsequent paragraphs of the Complaint that Defendants "manufactured" or "sold" Factor VIII and Factor IX and denies that Factor VIII and Factor IX are "products." Except as admitted or denied above, to the extent the matters set forth in Paragraph 1 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 1 of the Complaint.

2. Defendants manufactured HCV-contaminated blood factor products using human plasma taken from thousands of paid donors, including populations then known to be at high risk of carrying blood-borne diseases, such as urban homosexuals, prisoners, and intravenous drug users. Defendants intentionally recruited urban homosexuals who had a history of viral hepatitis as plasma donors, despite regulations prohibiting the use of such donors and despite knowledge that the virus that causes HCV was a blood-borne disease prevalent in such populations. Defendants continued using plasma taken from high-risk prison donors, even after promising the FDA that they would cease doing so. Through their trade associations, Defendants actively conspired to conceal these practices and to substantially delay product recalls and implementation of safety measures.

PARAGRAPH NO. 2 ANSWER: Bayer admits that it processed (in facilities in the United States) plasma taken from human donors who were compensated for their time and distributed Factor VIII and Factor IX for the treatment of hemophilia. Bayer admits that thousands of such donors were required to meet the medical needs for Factor VIII and Factor IX. Except as admitted above, to the extent the matters set forth in Paragraph 2 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 2 of the Complaint.

3. Defendants failed to fully and completely disclose the known risks of their products, including the risk of HCV; failed to implement readily available screening tests that would have prevented HCV by excluding contaminated plasma; failed to use available methods of treating plasma to kill viruses, including treatment with solvents and/or detergents; and concealed and affirmatively misrepresented the extent of the health dangers of the diseases caused by the products. Defendants also continued to sell old stocks of product that had not been treated even after introducing a safer treated product, including stocks that Defendants knew or had reason to know were made from pooled blood contaminated with HCV.

PARAGRAPH NO. 3 ANSWER: Bayer denies the allegations in the first sentence of Paragraph 3 of the Complaint. To the extent they are directed to Bayer and/or its predecessors, Bayer denies any remaining allegations in Paragraph 3 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 3 of the Complaint.

4. Defendants' efforts to maximize profits came at the expense of the health and lives of thousands of people with hemophilia in the United States and worldwide who were needlessly infected with HCV, including JAMES LANDMESSER, JR.

PARAGRAPH NO. 4 ANSWER: Bayer denies the allegations in Paragraph 4 of the Complaint.

II. ANSWER TO ALLEGATIONS REGARDING JURISDICTION AND VENUE

5. Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants.

PARAGRAPH NO. 5 ANSWER: Bayer admits that the Complaint purports to commence an action for certain damages. Bayer denies that it is liable for any damages and denies that Plaintiff is entitled to any relief against Bayer as requested in the Complaint. If the Plaintiff is, as he appears to allege, a citizen of Maryland, Bayer admits that there is complete diversity of citizenship and therefore this Court has jurisdiction under 28 U.S.C. § 1332.

6. Plaintiff resides in the State of Maryland and a significant portion of the conduct relevant to the subject matter of this case took place within this jurisdiction.

PARAGRAPH NO. 6 ANSWER: The allegations in Paragraph 6 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required and to the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 6 of the Complaint. To the extent that a response is required, Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 6 of the Complaint.

7. Plaintiff is informed and believes and on such information and belief alleges that Defendants do business within the State of Maryland and intended their products, put into the stream of commerce, to be purchased and used in the State of Maryland, giving this State significant contacts to the claims asserted by Plaintiff.

PARAGRAPH NO. 7 ANSWER: The allegations in Paragraph 7 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required and to the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 7 of the Complaint. To the extent that a response is required, Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 7 of the Complaint.

III. ANSWER TO ALLEGATIONS REGARDING PARTIES

8. Plaintiff JAMES LANDMESSER, JR., is a resident of Silver Spring, Maryland, who has hemophilia. Plaintiff has already provided Defendant with a confidential Preliminary Patient Profile Form ("PPPF"), with beginning Bates number L-PPF 005992. The PPPF contains substantial additional information regarding Plaintiff's claim.

PARAGRAPH NO. 8 ANSWER: Bayer admits that Plaintiff has provided a confidential PPF, with beginning Bates number L-PPF 005992. Bayer denies that it injured Plaintiff. To the extent matters set forth in Paragraph 8 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 8 of the Complaint.

9. Plaintiff was infected with HCV and experienced physical and emotional harm as a direct and proximate result of his use of Defendants' blood products.

PARAGRAPH NO. 9 ANSWER: Bayer denies the allegations in Paragraph 9 of the Complaint.

10. Plaintiff would not have chosen to be treated with Defendants' blood products, nor would have his guardians, had they known of or been informed by Defendants of the true risks of using those products or the nature of the sources of the products.

PARAGRAPH NO. 10 ANSWER: Bayer denies that it failed to advise of the risks of its Factor VIII and Factor IX. To the extent the remaining matters set forth in Paragraph 10 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 10 of the Complaint.

11. Defendant CUTTER BIOLOGICAL ("CUTTER"), the predecessor of Miles, Inc., and Defendant BAYER, was a California corporation headquartered in Berkeley, California at all pertinent times. At all pertinent times CUTTER and its successors Miles, Inc. and BAYER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor concentrates produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

PARAGRAPH NO. 11 ANSWER: Bayer admits that Cutter Laboratories, Inc. was a corporation with its headquarters in Berkeley, California until it ceased to exist as a separate corporation on January 1, 1983, and that Cutter was a predecessor of Miles, Inc. and a predecessor of Bayer. Bayer admits that it engaged in the collection of plasma and the

processing and distribution of Factor VIII and Factor IX produced from such plasma. Bayer denies the remaining allegations in Paragraph 11 of the Complaint.

12. Defendant BAYER CORPORATION ("BAYER"), formerly Miles, Inc., is and was an Indiana corporation, authorized to do business in all 50 states and the District of Columbia. Miles, Inc. had its principal place of business operation in Elkhart, Indiana, while its successor BAYER has its principal place of business in Pennsylvania, with offices located at 100 BAYER Road, Pittsburgh, Pennsylvania 15205. At all pertinent times BAYER and its predecessors Miles, Inc., and CUTTER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor concentrates produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

PARAGRAPH NO. 12 ANSWER: Bayer admits that it is a corporation organized and existing under the laws of the State of Indiana with its principal place of business in Pittsburgh, Pennsylvania, with offices located at 100 Bayer Road, Pittsburgh, Pennsylvania, and is and was authorized to do business in all fifty states, including the State of Illinois. Bayer admits that Miles, Inc. had its headquarters in Elkhart, Indiana. Bayer admits that it, Miles, Inc. and Cutter engaged in the collection of plasma and the processing and distribution of Factor VIII and Factor IX produced from such plasma. Bayer denies the remaining allegations in Paragraph 12 of the Complaint.

13. Defendant BAXTER HEALTHCARE CORPORATION ("BAXTER") is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015. At all times pertinent, Defendant BAXTER, and/or its HYLAND

DIVISION, had its main manufacturing plant in Glendale, California. At all times pertinent, Defendant BAXTER, and/or its HYLAND DIVISION, and/or its wholly owned subsidiaries Travenol Laboratories, regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sale and distribution of FACTOR CONCENTRATE products produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

PARAGRAPH NO. 13 ANSWER: Upon information and belief, Bayer admits that Baxter Healthcare Corporation is a Delaware corporation with its principal place of business in Illinois. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 13 of the Complaint.

14. Defendant ARMOUR PHARMACEUTICAL COMPANY, INC. ("ARMOUR") is a Delaware corporation, with its principal place of business in Pennsylvania, with offices located at 500 Arcola Road, P.O. Box 1200, Collegeville, Pennsylvania, 19426-0107. At all times pertinent, ARMOUR regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of factor concentrate products produced from such plasma, to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

PARAGRAPH NO. 14 ANSWER: Upon information and belief, Bayer admits that Armour Pharmaceutical Company is a Delaware corporation with its principal place of business in Pennsylvania. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 14 of the Complaint.

15. Defendant ALPHA THERAPEUTIC CORPORATION ("ALPHA") is a California corporation, with its principal place of business in California, with offices at 5555

Valley Boulevard, Los Angeles, California 90032. At all times pertinent, Defendant has been regularly and systematically engaged in the harvesting and collection of human plasma, and the processing, manufacturing, marketing, sale and distribution of factor concentrate products produced from such plasma to which Plaintiff was exposed and which contributed directly or indirectly to Plaintiff's infection with HCV.

PARAGRAPH NO. 15 ANSWER: Upon information and belief, Bayer admits that Alpha Therapeutic Corporation is a California corporation with its principal place of business in California. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 15 of the Complaint.

16. Defendants CUTTER, BAXTER, ARMOUR and ALPHA (hereinafter collectively referred to as "Defendants"), acting on behalf of themselves and/or their predecessor and/or successor corporations, collected, harvested and/or processed human plasma and/or manufactured, marketed, sold and distributed factor concentrate products that were contaminated with HCV. In the alternative, one or more of said Defendants participated in the collection, harvesting and/or processing of human plasma, and/or the manufacturing, marketing, distribution and sale of factor concentrate products, that were contaminated with HCV; or assumed or became responsible for, the liabilities of the Defendants and their predecessor or successor corporations who did participate in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution or sale of factor concentrate products, that were contaminated with HCV, without limitation thereto.

PARAGRAPH NO. 16 ANSWER: Bayer admits that Cutter engaged in the collection and processing of human plasma and the distribution of Factor VIII and Factor IX concentrate in the United States and in foreign countries. Except as admitted above, to the extent

the matters set forth in Paragraph 16 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 16 of the Complaint.

17. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions, and Defendants thereby ratified those actions.

PARAGRAPH NO. 17 ANSWER: The allegations in Paragraph 17 of the Complaint set forth conclusions of law to which no response is required. To the extent a response is required, and to the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 17 of the Complaint. To the extent that a response is required, Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 17 of the Complaint.

IV. ANSWER TO PLAINTIFF'S "FACTUAL ALLEGATIONS" APPLICABLE TO ALL CLAIMS

A. Answer to Allegations Regarding Hemophilia and Its Treatment

18. Hemophilia is an inherited condition that causes uncontrolled hemorrhaging or bleeding. Hemophilia results from a deficiency of blood components essential for coagulation. The most common form of the disease is hemophilia A, characterized by a lack of a blood protein known as Factor VIII, which affects approximately one in 10,000 males. Factor VIII is commonly called "AHF" or anti-hemophilic factor. Hemophilia B is characterized by absence of another blood protein, known as Factor IX, affecting about one in 40,000 males. Plaintiff JAMES LANDMESSER, JR. has severe hemophilia A.

PARAGRAPH NO. 18 ANSWER: Bayer admits that hemophilia is a fairly rare disorder present from birth in which the affected person is unable to produce adequate levels, necessary for normal clotting, of one or more proteins in the blood known as "factors". Bayer admits that a deficiency of Factor VIII, known as hemophilia A, is the most prevalent form of the illness and a deficiency of Factor IX is known as hemophilia B. Bayer admits that Factor VIII concentrates are commonly called "AHF." Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 18 of the Complaint.

19. The treatment of hemophilia involves intravenous introduction, called infusion, of the missing blood proteins required to stop bleeding. The two most prevalent forms of such treatment are cryoprecipitate and factor concentrates. Factor concentrates are the products made by Defendants in this action. Cryoprecipitate is made by freezing plasma, the fluid component of circulating blood in which various proteins, including Factor VIII and Factor IX, are contained; thawing the frozen plasma; and isolating Factor VIII from the plasma through centrifugal concentration. Cryoprecipitate is an effective therapeutic agent for patients with hemophilia A. Hemophilia B has been effectively treated with the use of fresh frozen plasma containing Factor IX. Cryoprecipitate and fresh frozen plasma are made from small numbers of donors, who are generally unpaid volunteers.

PARAGRAPH NO. 19 ANSWER: Bayer admits hemophilia is a fairly rare disorder present from birth in which the affected person is unable to produce adequate levels, necessary for normal clotting, of one or more proteins in the blood known as "factors." Bayer admits that factor concentrates are produced by a process consisting of several steps known collectively as "fractionation." Bayer denies that Factor VIII or Factor IX are products. Bayer admits that treatment of hemophilia can include intravenous introduction of missing blood components

essential for coagulation (sometimes referred to as "infusion") and that prevalent forms of such treatment include blood factor concentrates and cryoprecipitate. Bayer further admits that cryoprecipitate results from the freezing and thawing of human plasma which results in a material rich in Factor VIII and that cryoprecipitate is used to treat hemophilia A. Bayer admits that fresh frozen plasma contains some Factor IX and has been used to treat hemophilia B. Except as admitted or denied above, Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19 of the Complaint.

20. In the late 1960s to early 1970s, Defendants began to market factor concentrates, which contained Factor VIII and Factor IX in higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from five to over twenty thousand donors at a time, a large percentage of which were paid donors. These large pools were then subjected to processes to concentrate Factors VIII and IX.

PARAGRAPH NO. 20 ANSWER: Bayer admits that, beginning in 2068, it or one of its predecessors was licensed by the FDA to process and distribute Factor IX, and that, beginning in 2074, it or one of its predecessors was licensed by the FDA to process and distribute Factor VIII. Bayer admits that its Factor VIII concentrate contained higher concentrations of that protein than cryoprecipitate and than Factor VIII and Factor IX concentrate contained higher concentrations of these proteins than fresh frozen plasma. Cryoprecipitate does not contain Factor IX. Bayer admits that it processed plasma taken from human donors, some of whom were compensated for their time, and that their plasma was combined into "pools" and subject to a process, consisting of several steps, involving chemicals and other actions, known collectively as "fractionation" which had the effect of producing a

more concentrated form of Factor VIII and Factor IX. Except as admitted above, to the extent the matters set forth in Paragraph 20 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 20 of the Complaint.

B. Answer to Allegations Regarding Failure to Disclose or Warn

21. Shortly after the initial commercial marketing of Factor VIII and IX concentrates in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. By that time, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiff or the medical community of these adverse effects, violating industry standards and federal regulations.

PARAGRAPH NO. 21 ANSWER: Bayer admits that, in the late 1960's and early 1970's, the use of factor concentrates was known to cause adverse effects. Except as admitted above, Bayer denies the remaining allegations in Paragraph 21 of the Complaint.

22. By 1976, only a few years after Defendants' factor concentrate products went on the market, the United States Food and Drug Administration ("FDA") Bureau of Biologics held a conference titled *Unsolved Therapeutic Problems in Hemophilia*. The research articles compiled from the conference discussed the high incidence of disorders in patients using Defendants' products, such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B Hepatitis ("NANB Hepatitis," later renamed Hepatitis C). The articles concluded that these disorders were tied to the patients' use of factor concentrates, and emphasized the risks entailed in producing such concentrates using plasma from paid donors. For instance, Robert Gerety of the FDA

Bureau of Biologics, Division of Blood and Blood Products, reported that the agent or agents of NANB Hepatitis "appear to be blood borne, perhaps to be associated with a form of chronic hepatitis, and to represent a considerable risk to recipients who repeatedly require the administration of blood products." Gerety, et al., *Viral Antigens and Antibodies in People with Hemophilia* (1977). Gerety noted that "[t]he use of large plasma pools from paid donors no doubt contributes to the risk of HBV [Hepatitis B] infection from these products," and stated that "an all voluntary blood donor system is being pursued as a result of the known increased risk of PTH [post-transfusion hepatitis] from blood derived from commercial donors." As described below, however, Defendants not only refused to implement such a voluntary donor system, but instead recruited paid donors precisely because their hepatitis exposure resulted in plasma from which Defendants could make other commercially valuable products as well.

PARAGRAPH NO. 22 ANSWER: The allegations in Paragraph 22 of the Complaint refer to a conference and purport to characterize certain articles allegedly compiled from that conference. Those articles are in writing and speak for themselves. To the extent that Plaintiff's allegations regarding the content of those articles are inconsistent with the actual language of the articles or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 22 of the Complaint.

23. At all times material to this Complaint, Defendants failed to adequately warn Plaintiff or his physicians of the serious adverse side effects of their products. Although Defendants' package inserts mentioned a risk that plasma "may" contain the causative agent of viral hepatitis, the warning was seriously deficient in that: (a) Defendants failed to disclose that

the risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk donors and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b) while "hepatitis" simply means inflammation of the liver, and may be a relatively benign, temporary condition, Defendants failed to warn that some forms of hepatitis transmitted by their products were believed to present a considerable risk of severe liver damage and a significantly elevated risk of liver cancer; (c) Defendants misleadingly stated that the source plasma used in preparation of their products had been found to be non-reactive for Hepatitis B surface antigen (HBsAg)—implying that no viral hepatitis was present in the plasma—and falsely stated that available methods were not sensitive enough to detect all units of potentially infectious plasma, failing to disclose that in fact Defendants had refused to implement the more sophisticated Hepatitis B Core Antibody (HBc) test which would have excluded the majority of plasma contaminated by hepatitis; and (d) Defendants' labeling disclosed that their products were made from large pools of fresh human plasma, but failed to disclose that paid donors increased the risk of disease, and that the particular groups of paid donors targeted by Defendants were known to be the highest risk groups.

PARAGRAPH NO. 23 ANSWER: To the extent the matters set forth in Paragraph 23 of the Complaint are directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 23 of the Complaint.

24. The demand for and supply of anti-hemophilic factor rapidly increased during the 1970's, with commercially-manufactured concentrate accounting for a large proportion of the increase in supply. In 1977, a federal report projected that the volume of factor concentrates manufactured would increase substantially by 1980. Division of Blood Diseases and Resources,

National Heart, Lung and Blood Institute, *Study to Evaluate the Supply-Demand Relationships for AHF and PTC Through 1980*, at page 8; hereinafter "NHLBI Report."

PARAGRAPH NO. 24 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence in Paragraph 24 of the Complaint. The allegations in the second sentence in Paragraph 24 of the Complaint purport to refer to or describe a NHLBI report. Such report is in writing and speaks for itself. To the extent the allegations in the second sentence of Paragraph 24 are inconsistent with the NHLBI report, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

25. In order to sell more factor concentrates to this growing market, Defendants turned to the fastest and cheapest way of obtaining sufficient plasma, paid donors. Defendants recruited paid donors from those populations most likely to respond to the financial incentive to donate: poor inner city residents, drug abusers, prisoners, and residents of impoverished developing countries such as Haiti and Nicaragua.

PARAGRAPH NO. 25 ANSWER: Bayer denies the allegations in Paragraph 25 of the Complaint.

26. Defendants purposefully sought out paid donors despite knowing that the risk of diseases transmissible by blood was far greater among paid donors than among volunteers. Because no test was yet available in the 1970s for the NANB Hepatitis virus, an essential means to prevent the virus from contaminating the plasma supply was to exclude donors with behaviors that were inconsistent with good health—precisely those populations from which Defendants were recruiting paid donors. Some studies indicated that paid donors were up to ten times more infectious than volunteer donors. For this reason, the National Blood Policy, adopted by the

federal government in July 1973, advocated conversion to an all-volunteer blood supply. Defendants, however, not only continued to use paid donors, but also focused their recruiting efforts on the highest risk populations.

PARAGRAPH NO. 26 ANSWER: Bayer denies the allegations in Paragraph 26 of the Complaint.

27. Defendants had an additional financial incentive for recruiting paid donors. Factor VIII and Factor IX are only two of many products that can be made for commercial sale from human plasma. According to the NHLBI Report, by the late 1970s at least 17 different therapeutic components of blood were manufactured by the process of "fractionating" plasma into its various elements. The NHLBI Report noted that, "as the costs of fractionation have increased, fractionators have produced as many products as possible from a liter of plasma." *Id.* at 65.

PARAGRAPH NO. 27 ANSWER: The phrase "an additional financial incentive" is not a plain statement to which Bayer can or is required to respond. Bayer admits that therapeutic medication, in addition to Factor VIII and Factor IX, can sometimes be derived from the same unit of plasma. Except as admitted above, to the extent the matters set forth in the first and second sentences of Paragraph 27 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in the first and second sentences of Paragraph 27 of the Complaint. The allegations in the third and fourth sentences in Paragraph 27 of the Complaint purport to refer to or describe a NHLBI report. Such report is in writing and speaks for itself. To the extent the allegations in the third and fourth sentences of Paragraph 27 are inconsistent

with the NHLBI report, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

28. Blood derivatives used as vaccines or therapeutics had particularly high economic value for Defendants. The NHLBI Report noted that plasma with a very high titer, or antibody level, for a corresponding antigen is "very expensive." *Id.* at 41. Such products are manufactured from source plasma drawn from donors who have been sensitized to a particular antigen. *Id.* The NHLBI Report specifically stated, however, that "plasma collected for high antibody titer **cannot** be used for fractionation into therapeutic products," such as Defendants' factor concentrate. *Id.* (emphasis added).

PARAGRAPH NO. 28 ANSWER: The phrase "particularly high economic value" is not a plain statement to which Bayer can or is required to respond. The allegations in the reminder of Paragraph 28 of the Complaint purport to refer to or describe a NHLBI report. Such report is in writing and speaks for itself. To the extent the allegations in the remainder of Paragraph 28 are inconsistent with the NHLBI report, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 28 of the Complaint.

29. Defendants targeted donors with high titers to Hepatitis B antigens in order to manufacture and sell Hepatitis B immunoglobulin (HBIG), a product that confers temporary immunity to the Hepatitis B virus. Despite the warning in the NHLBI report, Defendants used the same high-titer plasma obtained for making HBIG to manufacture their Factor VIII and IX products used by people with hemophilia. Defendants thus sought to maximize profits by

producing "as many products as possible from a liter of plasma," while ignoring industry standards that precluded the use of high-titer plasma for other therapeutic products.

PARAGRAPH NO. 29 ANSWER: Bayer admits that HBIG confers temporary immunity to the Hepatitis B virus. Bayer denies that it manufactured or sold Factor VIII and/or Factor IX. Except as admitted or denied above, to the extent the matters set forth in Paragraph 29 of the Complaint are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 29 of the Complaint.

30. Beginning in about 1978, Defendants began targeting homosexual donors in known urban gay communities. Because urban homosexuals had been reported in the 1970s to have exceptionally high prevalence of Hepatitis B infection, Defendants knew that such donors would provide a reliable source of plasma for the manufacture of commercially valuable HBIG.

PARAGRAPH NO. 30 ANSWER: The phrase "targeting" is not a plain statement to which Bayer can or is required to respond. To the extent the matters set forth in Paragraph 30 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 30 of the Complaint.

31. By the 1970s, it was also well-known in the public health community that urban homosexuals engaged in promiscuous sexual practices that rapidly transmitted other diseases, including NANB Hepatitis, which were transmitted by blood and were believed to have serious

adverse consequences. Despite this knowledge, Defendants used the same plasma pool from urban homosexuals to manufacture both HBIG and Factor VIII and IX.

PARAGRAPH NO. 31 ANSWER: To the extent the matters set forth in Paragraph 31 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 31 of the Complaint.

32. By the 1970s, it was also well-established that plasma from prison populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of the concentration of intravenous (IV) drug users in prisons. By 1974, the alanine aminotransferase ("ALT") test was available to test for elevated levels of liver enzymes called SGOT that indicate the presence of hepatitis. Prisoners were associated with SGOT levels of over 60 IUs per ml, a level that increases the risk of Hepatitis C transmission by a factor of 6. Despite knowledge of this risk, Defendants actively recruited prisoners for plasma used to manufacture Factor VIII and IX, while concealing or failing to disclose the risk to Plaintiff, his physicians, or the FDA.

PARAGRAPH NO. 32 ANSWER: Bayer admits that ALT testing was available by 1974 to test for elevated levels of liver enzymes called SGOT. Except as admitted above, to the extent the matters set forth in Paragraph 32 of the Complaint are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 32 of the Complaint.

33. In light of Defendants' special knowledge of the disease patterns among urban homosexuals and prisoners, and their recruitment of such donors for Factor VIII and IX

manufacture, Defendants had duties to: (a) discontinue the practice of using such high risk donors; (b) disclose the risk to Plaintiff, his physicians, and the FDA, including the ongoing risk of continuing to use Factor VIII and IX previously manufactured with high risk plasma and still marketed to patients; (c) implement procedures to kill blood-borne diseases in the products; and (d) recall existing products from distribution or further use. Instead, Defendants continued to conceal their recruitment of high-risk donors and to resist warnings and recalls, and failed to implement procedures to make their products safe.

PARAGRAPH NO. 33 ANSWER: To the extent the allegations in Paragraph 33 of the Complaint are directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 33 of the Complaint.

34. By no later than 1978, Defendants knew of the availability of a new test to determine whether an individual had a history of viral hepatitis, which would have disqualified the donor from providing plasma for the manufacture of Factor VIII or IX. By testing a person's serum for the presence of the core to the Hepatitis B antibody, a history of viral hepatitis could be verified. This was known as the "HBc test." Published, peer-reviewed literature shows that the HBc test was in use by researchers to determine that homosexual AIDS victims had a history of viral hepatitis by no later than December 1981. Gottlieb, et al., *Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men*, 305 New Eng. J. Med. 1425-1431 (1981).

PARAGRAPH NO. 34 ANSWER: Some or all of the allegations in Paragraph 34 of the Complaint purport to refer to or describe a NHLBI report. Such report is in writing and speaks for itself. To the extent any remaining allegations of Paragraph 34 are inconsistent with

the NHLBI report, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

35. Use of the HBc test would have eliminated approximately 75% of homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have eliminated almost 100% of intravenous drug users.

PARAGRAPH NO. 35 ANSWER: Bayer denies the allegations in Paragraph 35 of the Complaint.

36. Use of the HBc and ALT tests together by Defendants by 1981 would have eliminated the vast majority of the transmitters of HCV from the blood and plasma pools of the nation, before the height of the Hepatitis C epidemic. If Defendants had implemented this test in a timely manner, Plaintiff more likely than not would not have been infected with HCV as a result of factor concentrate use.

PARAGRAPH NO. 36 ANSWER: Bayer denies the allegations in Paragraph 36 of the Complaint.

37. As noted below, federal regulations required plasma donors to be in good health, and donors with a "history of viral hepatitis" were by definition unacceptable as blood or blood plasma donors. Persons with a history of viral hepatitis were excluded not only because of the risk of transmitting Hepatitis B, but because such a history indicated a lifestyle or previous behavior of the prospective donor that carried the risk of transmitting other viruses in addition to hepatitis. A reasonable and prudent plasma fractionator would not accept a HBc positive donor and expect to be in compliance with federal regulations as of 1978.

PARAGRAPH NO. 37 ANSWER: The allegations in Paragraph 37 of the Complaint purport to quote from or characterize unspecified "federal regulations." Any federal

regulation is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of the federal regulation are inconsistent with the actual language of the regulation, Bayer denies them. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 37 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 37 of the Complaint.

38. After public reports of the first hemophilia AIDS cases in July 1982, government officials urged Defendants to implement the HBc test as a "surrogate" or "marker" to eliminate plasma contaminated by the transmitter of AIDS and Hepatitis C. HBc testing was also strongly suggested to Defendants by the CDC at a meeting of the United States Public Health Service ("PHS") on January 4, 1983. Despite this urging, Defendants continued to use contaminated plasma donations that would have been excluded by the HBc test and continued to conceal from Plaintiff, his physicians, and the FDA the dangerous practice of targeting donors at highest risk for hepatitis. At a January 6, 1983 meeting of Defendants' trade association, the Pharmaceutical Manufacturer's Association, Defendants agreed not to implement the highly effective HBc donor screening, and instead opted to use ineffective donor questionnaires that did little to screen out donors at high-risk for Hepatitis C transmission.

PARAGRAPH NO. 38 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence in Paragraph 38 of the Complaint. To the extent they are directed to Bayer and/or its predecessors, Bayer denies

any remaining allegations in Paragraph 38 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 38 of the Complaint.

39. As late as December 13, 1983, years after the HBc test was available, a memorandum from CUTTER's responsible head, Stephen Ojala, reporting back on a meeting held by Defendants, shows that Defendants conspired to propose a "task force" to further study the use of HBc as an intentional, bad faith "delaying tactic for the implementation" of the test.

PARAGRAPH NO. 39 ANSWER: The allegations in Paragraph 39 of the Complaint purport to refer to or describe a document. That document is in writing. To the extent allegations in Paragraph 39 are inconsistent with the document, Bayer denies them. Bayer admits that in December 1983, certain representatives of the plasma industry, BPAC and the FDA were present at a meeting where the creation of a Task Force to evaluate and study the utility of HBc testing was proposed. Bayer denies that it conspired with anyone and denies that the proposed evaluation of HBc testing by Bayer was proposed in bad faith or was intended to be an improper delaying tactic. To the extent the allegations in Paragraph 39 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 39 of the Complaint.

C. Answer to Plaintiff's Allegations Regarding Solvent Detergent

40. In the late 1970s and early 1980s, it was recognized that viruses were in all factor concentrate products. Treatment with solvents and/or detergents was available at that time to eliminate many of these viruses, including HCV. Defendants were required to take reasonable

steps to eliminate contamination, but Defendants failed to utilize these available technologies to eliminate the viruses in a timely manner.

PARAGRAPH NO. 40 ANSWER: Bayer admits that in the late 1970's to early 1980's, hepatitis was a known, accepted and warned of risk associated with the use of Factor VIII and Factor IX. Bayer admits that some "[t]reatment with solvents and/or detergents" kill HCV. Bayer denies that such a treatment was "available" in "the late 1970's" and denies that all solvent detergent treatments kill HCV. To the extent the matters set forth in Paragraph 40 of the Complaint are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 40 of the Complaint.

41. Solvent and/or detergent treatment was available to Defendants by the late 1970s as a simple and effective method of eliminating viruses in factor concentrate products. Solvents and/or detergents effectively kill viruses such as HCV by destroying the viruses' lipid envelope. This method is simpler than heat treatment, and unlike heat treatment does not interfere with the Factor VIII and IX proteins needed for blood clotting.

PARAGRAPH NO. 41 ANSWER: Bayer admits that some treatments involving solvent and/or detergent kill HCV by action on the lipid envelope. Bayer denies that such treatments are simple and denies that a solvent detergent treatment was "available" in "the late 1970's" and denies that all solvent detergent treatments kill HCV. To the extent the matters set forth in Paragraph 41 of the Complaint are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer

denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 41 of the Complaint.

42. Solvents and/or detergents were well-known, commercially available products as of the 1970s, and studies in which solvent and/or detergent treatment was used to disrupt viruses were published in the 1970s in peer-reviewed journals. In 1980, Dr. Edward Shanbrom, a former Baxter scientist, received a patent for a detergent treatment process for viral inactivation of factor concentrate. Dr. Shanbrom describes the implementation of this process as "as easy as washing your hands."

PARAGRAPH NO. 42 ANSWER: The allegations in the first sentence of Paragraph 42 of the Complaint refer to or describe certain unidentified studies involving solvent detergents and viruses. To the extent such studies exist, they are in writing and speak for themselves. To the extent that Plaintiff's allegations regarding the content of those studies are inconsistent with the actual language of the studies or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer admits that Dr. Shanbrom is a former Baxter scientist. To the extent the matters set forth in the second and third sentences of Paragraph 42 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 42 of the Complaint.

43. After receiving the patent, Dr. Shanbrom approached Defendants about implementing his method, but Defendants refused to heed Dr. Shanbrom's advice. Defendants refused to even commit any resources to investigate the solvent and/or detergent method.

PARAGRAPH NO. 43 ANSWER: Bayer denies that it wrongfully refused to investigate or implement the solvent detergent "method." To the extent the remaining matters set forth in Paragraph 43 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 43 of the Complaint.

44. Defendants were notified of the successful use of organic solvents to destroy lipid viruses, including NANB, in factor concentrates by the New York Blood Center ("NYBC") at the National Hemophilia Federation's meeting on October 27, 1983.

PARAGRAPH NO. 44 ANSWER: Bayer admits that the New York Blood Center (hereinafter "NYBC") gave a presentation at the NHF's National Meeting in October, 1983. To the extent the remaining matters set forth in Paragraph 44 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 44 of the Complaint.

45. In 1984, Dr. Prince and Dr. Horowitz of the NYBC published the results of their successful use of the solvent detergent process in well-known medical journals. They offered to license the process to Defendants for a reasonable fee. In 1985, the NYBC obtained a license from the FDA to market a solvent detergent inactivated factor concentrate.

PARAGRAPH NO. 45 ANSWER: The allegations in the first sentence of Paragraph 45 of the Complaint purport to refer to or describe one or more publications. Such publications are in writing and speak for themselves. To the extent the allegations in the first sentence of Paragraph 45 are inconsistent with those publications, or are intended to constitute

allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer admits that the NYBC offered to license its process for a fee and that the NYBC obtained a license from the FDA to market a solvent detergent inactivated factor concentrate in 1985. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 45 of the Complaint.

46. By March, 1984, Defendants obtained licenses to sell Factor VIII treated with dry heat to inactivate viruses, and Defendants had obtained such licenses for Factor IX by October, 1984. The FDA did not allow them to label the products as hepatitis safe. By fall of 1984, Defendants were notified by treaters that previously-untreated patients in their clinical trials using their dry heated product developed elevated ALT enzymes, indicative of NANB infections.

PARAGRAPH NO. 46 ANSWER: Bayer admits that Cutter had obtained a license to distribute Koate HT by March, 1984. Bayer admits that Cutter obtained a license to distribute Konyne HT in October, 1984. Bayer admits that the FDA did not allow Bayer to label its dry heat treated factor concentrates as hepatitis safe. Bayer denies that by fall of 1984, it was notified by treaters that previously-untreated patients using dry heated product developed ALT enzymes. Bayer also denies that an elevated ALT level is always proof of a NANB infection. Except as admitted or denied above, to the extent the matters set forth in Paragraph 46 of the Complaint are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 46 of the Complaint.

47. Defendants were therefore aware in 1984 that dry heat did not effectively inactivate the virus that causes HCV, and that solvent detergent treatment methods did eliminate the risk of HCV infection, but chose not to employ the effective and efficient solvent detergent technology. Instead, Defendants continued to sell their contaminated dry heat product for at least four more years, resulting in the needless infection of Plaintiff and many other hemophiliacs.

PARAGRAPH NO. 47 ANSWER: Bayer denies the allegations in Paragraph 47 of the Complaint.

48. A recent CDC study documented the comparative effectiveness of the dry heat and solvent detergent inactivation methods. The study reported that "84% of previously untreated patients infused with dry-heated Factor VIII products developed non-A, non B hepatitis . . . ." Soucie, Richardson, Evatt et al., *Risk Factor for Infection with HBV and HCV in a Large Cohort of Hemophiliac Males*, 41 Transfusion 338-343 (2001).

PARAGRAPH NO. 48 ANSWER: The allegations in Paragraph 48 of the Complaint purport to refer to or describe a CDC study. Such study is in writing and speaks for itself. To the extent the allegations in Paragraph 48 are inconsistent with the CDC study, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

49. The same CDC study reported that "solvent detergent treatment of blood components [was] found to be more effective against enveloped viruses than heat treatment ... No cases of HBV, HCV, or HIV transmission through solvent detergent virus inactivated products have been found in prospective studies of previously untreated patients..."

PARAGRAPH NO. 49 ANSWER: The allegations in Paragraph 49 of the Complaint purport to refer to or describe a CDC study. Such study is in writing and speaks for

itself. To the extent the allegations in Paragraph 49 are inconsistent with the CDC study, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

50. The study further reported "in our data, the first dramatic decline in HCV prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the licensing of solvent detergent treatment of Factor IX products in 1987. In addition, this cohort would have been the first to benefit from the screening of blood donors using the surrogate markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with a markedly decreased risk of HCV infection from blood transfusions."

PARAGRAPH NO. 50 ANSWER: The allegations in Paragraph 50 of the Complaint purport to refer to or describe a CDC study. Such study is in writing and speaks for itself. To the extent the allegations in Paragraph 50 are inconsistent with the CDC study, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them.

51. The study states further that "the residual transmissions after 1987 possibly represent the use of product already manufactured or product manufactured during the interval required to implement the new technology. The 18-month shelf life of factor concentrates placed those people with hemophilia born as late as 1989 at risk of infection." The study goes on to recommend testing for all people with hemophilia who received infusions of Defendants' blood products prior to 1992.

PARAGRAPH NO. 51 ANSWER: The allegations in Paragraph 51 of the Complaint purport to refer to or describe a CDC study. Such study is in writing and speaks for itself. To the extent the allegations in Paragraph 51 are inconsistent with the CDC study, or are

intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies those allegations.

52. By 1988, it was clear to the medical and scientific community what Defendants had long known: dry-heated factor concentrates were transmitting the potentially deadly NANB virus, and safer products were available. This knowledge prompted the CDC to publish recommendations that dry-heated products no longer be used by hemophiliacs. Defendants continued sales of their dry-heated products after these warnings, however, and never undertook a large-scale recall of dry-heated product. Defendants finally introduced solvent detergent-treated products to the market in 1988 and 1989, but continued to sell their NANB-contaminated dry-heated factor concentrates after this date.

PARAGRAPH NO. 52 ANSWER: Bayer admits that it introduced solvent detergent-treated factor VIII in 1989. Bayer denies that it introduced solvent detergent-treated Factor IX in 1988 or 1989. Some of the allegations in Paragraph 52 of the Complaint purport to refer to, or describe published CDC information and recommendations. Such information and recommendations are in writing and speak for themselves. To the extent the allegations in Paragraph 52 are inconsistent with the CDC information and recommendations, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. To the extent the remaining matters set forth in Paragraph 52 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 52 of the Complaint.

53. The failure of Defendants to implement solvent and/or detergent viral inactivation techniques in a timely manner, to warn of the risk that dry heat treated Factor VIII and IX blood products could transmit HCV, and to recall dry heat-treated products that posed this risk caused the needless infection of thousands of people with hemophilia with HCV, including Plaintiff. Even after Defendants knew or should have known that solvent and/or detergents effectively destroyed HCV, they continued to sell dry heat-treated Factor VIII and IX, and refused to recall these dangerous products from the market.

PARAGRAPH NO. 53 ANSWER: Bayer denies the allegations in Paragraph 53 of the Complaint.

D. Answer to Allegations of Misrepresentation and Fraudulent Concealment

54. Defendants engaged in a pattern and practice of fraudulent concealment of their dangerous practices, fraudulent misrepresentations regarding their efforts to assure safety, and fraudulent misrepresentations regarding the risk of Hepatitis C, in order to maintain profits from both factor concentrates and HBIG. A summary of Defendants' fraudulent misrepresentations and concealment is set forth below.

PARAGRAPH NO. 54 ANSWER: Bayer denies the allegations in Paragraph 54 of the Complaint.

55. On July 27, 1982, a meeting of the Public Health Service was held as the result of the CDC's report that three people with hemophilia had contracted AIDS. The responsible heads of Defendants were in attendance, along with officials from the National Hemophilia Foundation, CDC and FDA. Defendants were aware that they had used plasma from known, targeted homosexuals in the manufacture of their Factor VIII and IX blood products. These products had a shelf life of two years and were either in production or already on the shelves in

pharmacies waiting to be infused by people with hemophilia who purchased them. Defendants failed to disclose these facts at the meeting where CDC officials were present, despite knowledge that the CDC's primary concern at that meeting was the contamination of Factor VIII and IX by the agent that transmitted AIDS, which, like hepatitis, was already well-known to be epidemic in the targeted homosexual population. (CUTTER memorandum dated August 3, 1982.)

PARAGRAPH NO. 55 ANSWER: Bayer admits that on July 27, 1982, a meeting was held and the "responsible head" of Cutter was in attendance, along with officials from the National Hemophilia Foundation (hereinafter referred to as "NHF"), the CDC, the FDA and numerous others. The allegations in Paragraph 53 of the Complaint purport to refer to, or describe Defendants' internal communications. Such communications are in writing. To the extent allegations in Paragraph 55 are inconsistent with Defendants' internal communications, Bayer denies them. Except as admitted or denied above, to the extent the matters set forth in Paragraph 55 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 55 of the Complaint.

56. In or about December, 1982, Rodell, the responsible head for BAXTER, entered into an agreement with officials of the FDA to the effect that BAXTER would no longer use prison plasma in the production of factor concentrates. In fact, BAXTER, unbeknownst to the FDA, continued to use prison plasma in factor concentrate production through October 1983. BAXTER memorandum dated October 20, 1983.

PARAGRAPH NO. 56 ANSWER: Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56 of the Complaint.

57. On January 5, 1983, an AIDS meeting was held at Children's Orthopedic Hospital in Los Angeles, California, the largest hemophilia treatment center in the United States. Representatives of Defendants were present at the meeting with treaters and patients. A patient asked representatives from Defendants the following question: "Is the plasma from homosexuals, prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?" Defendants did not admit targeting or using plasma from homosexuals, prisoners or inner city IV drug abusers. Defendants' representatives made no response to the question, thereby concealing the true risk created by the use of plasma from known homosexuals, IV drug abusers and prisoners in the manufacture of factor concentrates.

PARAGRAPH NO. 57 ANSWER: Bayer admits that on January 5, 1983 a meeting was held at Children's Orthopedic Hospital in Los Angeles, California. Bayer admits that a Cutter representative was in attendance at that meeting. Bayer denies that any Cutter representative made any misleading statements. Except as admitted or denied above, to the extent the matters set forth in Paragraph 57 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 57 of the Complaint.

58. At the January 5, 1983 meeting, and in the presence of the patients, one of the treating physicians, Dr. Kasper, asked CUTTER'S Stephen Ojala: "These [plasma] centers seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti, Seattle, Clayton, NC., and San Diego. We do not have centers in L.A. or San Francisco." This answer was misleading because Ojala failed to state that CUTTER'S largest and first plasma

center was located at Arizona State Penitentiary. CUTTER also had a center at the Las Vegas Prison. Ojala and CUTTER were well aware of the CDC's and FDA's concern over use of prison plasma, due to homosexual practices and drug abuse in the prison donor population. Many of CUTTER'S centers were in inner city areas frequented by IV drug abusers, such as downtown Oakland, California. CUTTER had also used plasma from centers which targeted known homosexuals. In August 1982, CUTTER quarantined plasma from the Valley Medical Center, a center which targeted known homosexuals, because a donor was hospitalized with full blown AIDS. The plasma was intended for factor concentrate and HBIG production, but was not used because it had thawed on the way to the processing plant. Upon receiving a report of this incident from CUTTER, the FDA indicated a recall might have been necessary if the plasma had been incorporated into factor concentrate final product. Ojala omitted any mention of these facts and circumstances in his response to Dr. Kasper regarding the location of their plasma centers. (CUTTER memorandum dated January 5, 1983.)

PARAGRAPH NO. 58 ANSWER: Bayer admits that it obtained plasma from collection centers in Arizona, Las Vegas, Nevada and Oakland, California. Bayer denies that any Cutter representative made any misleading statements. The allegations in Paragraph 58 of the Complaint purport to refer to, or describe Defendants' internal communications. Such communications are in writing. To the extent allegations in Paragraph 58 are inconsistent with Defendants' internal communications, Bayer denies them. Except as admitted or denied above, to the extent the matters set forth in Paragraph 58 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 58 of the Complaint.

59. On January 14, 1983, responsible heads from Defendants attended a meeting of the National Hemophilia Foundation ("NHF"). Defendants were very concerned that the NHF would insist on a recommendation that HBc testing be implemented, consistent with the CDC recommendation 10 days earlier. In order to defer a NHF recommendation that HBc testing be used, Michael Rodell, a representative of BAXTER, told NHF officials on behalf of Defendants, that surrogate testing was in the "R and D," or "Research and Development," stage currently. Rodell concealed the fact that the CDC had strongly recommended use of the HBc antibody test as a screening device for high risk donors. The HBc antibody test was not in the "R and D" stage, and was suitable for use as a screening device for high risk AIDS and Hepatitis C donors. In fact, the HBc test had been approved in 1979 by the FDA as a test to be used to ascertain a history of previous hepatitis B infection, and to screen blood and plasma donors. Donors with a hepatitis history were specifically prohibited pursuant to the federal regulations (21 C.F.R. § 640.63). Rodell acknowledged that implementation of the HBc test would eliminate high titered immunoglobulin donors, but failed to disclose that opposition to use of the test was based on economic rather than safety concerns.

PARAGRAPH NO. 59 ANSWER: Bayer admits that a representative attended a meeting on January 14, 1983 with the NHF. To the extent the matters set forth in Paragraph 59 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 59 of the Complaint.

60. At the January 14, 1983 meeting, Defendants concealed their advertising in publications distributed among urban homosexuals, for the specific purpose of attracting them

to plasma centers which supplied high titered plasma to Defendants. Defendants also concealed their extensive use of prison plasma, and failed to reveal their "gentlemen's agreement" with the FDA to discontinue use of these plasma sources immediately. (CUTTER Memorandum dated January 17, 1983.)

PARAGRAPH NO. 60 ANSWER: Some or all of the allegations in Paragraph 60 of the Complaint purport to refer to, describe or be based on a "Cutter Memorandum". Such a document is in writing. To the extent the allegations in Paragraph 60 are inconsistent with that document, or are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. To the extent the remaining matters set forth in Paragraph 60 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 60 of the Complaint.

61. On or about December 15, 1983, Rodell, then the head of Armour Pharmaceutical Company, Inc., told members of the federal Blood Product Advisory Committee (BPAC) and FDA officials that Defendants wanted a three-month deferral in implementation of any recommendations by the BPAC or FDA that HBc testing be required for plasma donors. Rodell told the FDA that the purpose of the deferral was to prepare a response to the proposed recommendation. In fact, Defendants had agreed to seek the three-month hiatus as a "delaying tactic" against implementing the test, and the request for a deferral was made in bad faith. (CUTTER memorandum dated December 13, 1983.)

PARAGRAPH NO. 61 ANSWER: Bayer admits that, at a meeting on or about December 15, 1983, Michael Rodell proposed to members of the Blood Products Advisory

Committee and FDA officials the creation of a Task Force to evaluate HBc testing and requested an additional three months to provide more information about its use. Bayer denies that this was in any way intended to create an improper delaying tactic or was done in bad faith. Some or all of the allegations in Paragraph 61 of the Complaint purport to refer to, describe or be based on a "Cutter Memorandum". That document is in writing. To the extent the allegations in Paragraph 61 are inconsistent with the document Bayer denies them. Except as admitted or denied above, to the extent the remaining matters set forth in Paragraph 61 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 61 of the Complaint.

62. Defendants fraudulently misrepresented the risk of Hepatitis C due to factor concentrates, failed to disclose accurate warnings of the risk to Plaintiff or his physicians, and fraudulently purported to be doing "everything possible" to improve safety, when in fact Defendants maximized the risk by recruiting high-risk donors and by resisting and obstructing HBc testing, treatment with solvents and/or detergents, and other measures that would truly have reduced the risk.

PARAGRAPH NO. 62 ANSWER: Bayer denies the allegations in Paragraph 62 of the Complaint.

E. Answer to Allegations Regarding Federal Regulations

63. Blood derivatives such as Factor VIII and IX are prescription biologicals subject to federal regulation as both "biological products" and "drugs." Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 263; Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.* (2005).

(a) 21 U.S.C. § 331(b) prohibited and continues to prohibit "adulteration or misbranding of any ... drug . . . ."

(b) 21 U.S.C. § 351(a)(2)(B) provided and continues to provide that "[a] drug . . . shall be deemed to be adulterated . . . if ... the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety. . . ."

(c) 21 U.S.C. § 352 provided and continues to provide that "[a] drug... shall be deemed to be misbranded. .. if its labeling is false or misleading in any particular."

(d) 21 U.S.C. § 352(f)(2) provided and continues to provide that a drug shall be deemed to be "misbranded" unless its labeling bears "adequate warnings against use. . . where its use may be dangerous to health."

(e) 21 U.S.C. § 352(n) provided and continues to provide that a drug shall be deemed to be "misbranded" unless the labeling included information concerning side effects and contraindications as required in federal regulations.

(f) 21 U.S.C. § 321(n) provided and continues to provide that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account "not only representations made or suggested" by affirmative statements, "but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use" of the drug.

PARAGRAPH NO. 63 ANSWER: The allegations in Paragraph 63 of the Complaint purport to quote from sections of the United States Code. The United States Code is

in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of the United States Code are inconsistent with the actual language of the United States Code, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 63 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 63 of the Complaint.

64. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided and continues to provide as follows, with respect to information to be provided with the sale of Defendants' products:

> Warnings: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association with a drug; a causal relationship need not have been proved.

PARAGRAPH NO. 64 ANSWER: The allegations in Paragraph 64 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 64 are intended to constitute allegations of a defect,

wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 64 of the Complaint.

65. At all times material to this Complaint, 21 C.F.R. § 200.5 provided and continues to provide as follows:

> Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail shall be distinctive in appearance so that it will be promptly recognized and read.

PARAGRAPH NO. 65 ANSWER: The allegations in Paragraph 65 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 65 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 65 of the Complaint.

66. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth and continues to set forth "Current Good Manufacturing Practices" for biological products generally, and 21 C.F.R. § 640, *et seq.*, set forth additional good manufacturing practices for blood and plasma biologicals.

PARAGRAPH NO. 66 ANSWER: The allegations in Paragraph 66 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 66 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 66 of the Complaint.

67. At all times material to this Complaint, 21 C.F.R. § 606.140(a) provided and continues to provide:

> Laboratory control procedures shall include: The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

PARAGRAPH NO. 67 ANSWER: The allegations in Paragraph 67 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 67 are intended to constitute allegations of a defect,

wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 67 of the Complaint.

68. At all times material to this Complaint, 21 C.F.R. § 640.60 defined and continues to define "Source Plasma" as:

> the fluid portion of human blood collected by plasmapheresis, and is intended as source material for further manufacturing use.

PARAGRAPH NO. 68 ANSWER: The allegations in Paragraph 68 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 68 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 68 of the Complaint.

69. At all times material to this Complaint, 21 C.F.R. § 640.63(c), (1999), titled "Qualification of Donor," provided and continues to provide as follows with respect to donors of source plasma:

> Donors shall be in good health on the day of donation, as indicated in part by: . . . (9) freedom from any disease, other than malaria, transmissible by blood transfusion, in so far as can be determined by history and examination indicated in this section; (10) freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-

> injected narcotics; (11) freedom from a history of viral hepatitis; (12) freedom from a history of close contact within six months of donation with an individual having viral hepatitis; . . . .

(i) Further, 21 C.F.R. § 640.63(a) provided and continues to provide that the method of determining "suitability of a donor" included "tests" as well as the taking of a history and physical examination.

PARAGRAPH NO. 69 ANSWER: The allegations in Paragraph 69 of the Complaint purport to quote from sections of the Code of Federal Regulations. The Code of Federal Regulations is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of the Code of Federal Regulations are inconsistent with the actual language of the Code of Federal Regulations, Bayer denies those allegations. Bayer further states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 69 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 69 of the Complaint.

70. The foregoing statutes and regulations are evidence of the standard of care Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX. Defendants violated the foregoing regulations and/or failed to comply with applicable standards of care by: (a) marketing "adulterated" products that were unsafe as a result of failure to comply with "Current Good Manufacturing Practice"; (b) marketing "misbranded" products that were misleading and failed to disclose or warn of health dangers; (c) failing to warn of serious adverse reactions and potential safety hazards as soon as there was reasonable evidence of an association

with their products; (d) failing to exclude intravenous drug users who were unsuitable donors; (e) failing to exclude donors with a history of viral hepatitis who were unsuitable donors; (f) affirmatively seeking out unsuitable donors known to have viral hepatitis antibodies, as well as prison populations known to include substantial numbers of intravenous drug users, for inclusion of their plasma in the pools used to make Factor VIII and Factor IX; (g) failing to disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures to assure their products were safe.

PARAGRAPH NO. 70 ANSWER: The allegations in Paragraph 70, including subparagraphs (a) through (h), of the Complaint state conclusions of law to which no response is required. To the extent that a response is required and to the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 70 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 70 of the Complaint.

F. Answer to Allegations regarding Group Liability

71. All of the Defendants likely to have caused the harm to Plaintiffs are parties to this lawsuit and properly before the court.

PARAGRAPH NO. 71 ANSWER: The allegations in Paragraph 71 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 71 of the Complaint.

72. The conduct of Defendants, with respect to their Factor VIII and Factor IX products and related plasma collection methods, was tortious.

PARAGRAPH NO. 72 ANSWER: The allegations in Paragraph 72 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 72 of the Complaint.

73. The harm which has been caused to Plaintiffs resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of the Plaintiffs, there may be uncertainty as to which one or combination of Defendants caused the harm.

PARAGRAPH NO. 73 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 73 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 73 of the Complaint.

74. The burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiff.

PARAGRAPH NO. 74 ANSWER: The allegations in Paragraph 74 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 74 of the Complaint.

75. Factor concentrates were manufactured using the same fractionation method by all Defendants. As such, during the relevant years, factor concentrates were a fungible product, and physicians prescribed the products interchangeably without regards to brand names.

PARAGRAPH NO. 75 ANSWER: Bayer again denies that factor concentrates were manufactured. Bayer denies that Bayer's fractionation methods were the same as those used by the other Defendants. Bayer denies that factor concentrates were fungible or were, in all cases, prescribed interchangeably. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 75 of the Complaint.

76. The factor concentrates manufactured by Defendants contained the same design flaws. They were all manufactured from paid donor plasma, which was at highest risk for Hepatitis B and Hepatitis C viral transmission. In addition, all Defendants' factor concentrates were made from large pools consisting of 5,000 to over 20,000 paid donors, which further magnified the risk of viral transmission.

PARAGRAPH NO. 76 ANSWER: Bayer admits it processed factor concentrates from pooled plasma from multiple donors; some of whom were compensated for the time they spent making donations. Bayer denies that those donors were at high risk for Hepatitis B and Hepatitis C. Bayer denies that factor concentrates were "designed" or manufactured. To the extent the remaining matters set forth in Paragraph 76 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 76 of the Complaint.

77. None of the factor concentrates made by Defendants during the relevant time period were subjected to viral inactivation processes such as solvent and/or detergent treatment that were effective against HCV. Therefore, all of Defendants' factor concentrates carried a significant risk of HCV transmission during this time. In addition, all of Defendants' factor concentrate products were similarly misbranded. All of the products failed to warn of the known risks enumerated in this complaint.

PARAGRAPH NO. 77 ANSWER: Bayer denies the allegations in Paragraph 77 of the Complaint.

IV. ANSWER TO ALLEGATIONS REGARDING TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

78. Any and all potentially applicable statutes of limitations have been tolled by Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation. Such acts include but are not limited to intentionally covering up and refusing to disclose use of high-risk plasma; selling products known to be contaminated; suppressing and subverting medical and scientific research; and failing to disclose and suppressing information concerning the risk of HCV transmission from Defendants' contaminated factor concentrate.

PARAGRAPH NO. 78 ANSWER: The allegations in Paragraph 78 of the Complaint state conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 78 of the Complaint.

79. Defendants are estopped from relying on any statutes of limitation because of their fraudulent concealment and misrepresentation alleged above. Defendants were under a duty to disclose the precise risks of HCV transmission from their contaminated factor concentrate because this is nonpublic information over which they had exclusive control, because Defendants knew this information was not readily available to people with hemophilia like Plaintiff, and because this information was relevant to such people in deciding whether to use Defendants' factor concentrate.

PARAGRAPH NO. 79 ANSWER: The allegations in Paragraph 79 of the Complaint state conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 79 of the Complaint.

80. Until very recently, Plaintiff had no knowledge that Defendants were engaged in much of the wrongdoing alleged herein. Because of the fraudulent and active concealment of the

wrongdoing by Defendants, including but not limited to deliberate efforts—which continue to this day—to give Plaintiff the materially false impression that Defendants undertook all feasible safety precautions to reduce the risk of HCV transmission from their contaminated factor concentrates, Plaintiff could not reasonably have discovered the wrongdoing any time prior to this time, nor could Plaintiff have, as a practical matter, taken legally effective action given the unavailability, until very recently, of internal memoranda and other documents (as generally described herein) as evidence in support of Plaintiff's claims. Defendants still refuse to admit and continue to conceal their wrongdoing, and therefore Defendants' acts of fraudulent concealment and misrepresentation continue through the present time.

PARAGRAPH NO. 80 ANSWER: Bayer denies the allegations in Paragraph 80 of the Complaint, except that Bayer is without knowledge or information sufficient to form a belief as to the truth of allegations in the first sentence in Paragraph 80 of the Complaint regarding what Plaintiff allegedly knew or when they allegedly knew it.

V. ANSWER TO ALLEGATIONS REGARDING CLAIMS FOR RELIEF

Answer to Plaintiff's Fraudulent Omission and Concealment Allegations

81. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

PARAGRAPH NO. 81 ANSWER: Bayer incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

82. Defendants had a confidential and special relationship with Plaintiff due to: (a) Defendants' vastly superior knowledge of the health and safety risks relating to Factor VIII and Factor IX; (b) Defendants' sole and/or superior knowledge of their dangerous and irresponsible plasma collection practices; and (c) Defendants' direct communications with the hemophiliac

community through newsletters that purported to accurately convey the risk of NANB. As a result, Defendants had an affirmative duty to fully and adequately warn the hemophiliac community, including Plaintiff, his guardians and his physicians, of the true health and safety risks related to their Factor VIII and Factor IX blood products and constituent plasma, and a duty to disclose their dangerous and irresponsible plasma collection practices. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of their products to Plaintiff, his guardians and his physicians.

PARAGRAPH NO. 82 ANSWER: The allegations in Paragraph 82 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 82 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 82 of the Complaint.

83. Misrepresentations made by Defendants about the health and safety of their factor concentrate products independently imposed a duty upon Defendants to fully and accurately disclose to the hemophiliac community, including Plaintiff, his guardians and his physicians, the true health and safety risks related to Factor VIII and Factor IX and its constituent plasma, and a duty to disclose their dangerous and irresponsible plasma collection practices.

PARAGRAPH NO. 83 ANSWER: The allegations in Paragraph 83 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 83 of the Complaint.

84. In connection with their Factor VIII and Factor IX products, Defendants fraudulently and intentionally concealed important and material health and safety product risk information from Plaintiff, his guardians, the hemophiliac community, and treating physicians, all as alleged in this Complaint.

PARAGRAPH NO. 84 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 84 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 84 of the Complaint.

85. Any of the following is sufficient to independently establish Defendants' liability for fraudulent omission and/or concealment:

a. Defendants fraudulently concealed the health and safety hazards, symptoms, diseases and/or health problems associated with their Factor VIII and Factor IX blood products and related plasma collection activities;

b. Defendants fraudulently concealed the practice of using unsuitable plasma from unsuitable donors in the manufacture of their Factor VIII and Factor IX blood products;

c. Defendants fraudulently concealed their practice of avoiding the use of available technology to detect viruses in their Factor VIII and Factor IX blood products and the components thereof;

d. Defendants fraudulently concealed their practice of avoiding the use of available technology to destroy viruses in their Factor VIII and Factor IX blood products and the components thereof; and/or

e. Defendants fraudulently concealed information about the known comparative risks and benefits of the use of their Factor VIII and Factor IX and the relative benefits and availability of alternate products and therapies.

PARAGRAPH NO. 85 ANSWER: The allegations in Paragraph 85, including subparagraphs (a) through (e), of the Complaint set forth conclusions of law to which no

response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 85, including subparagraphs (a) through (e), of the Complaint.

86. Defendants knew that Plaintiff, his guardians, the hemophiliac community, and physicians would regard the matters Defendants concealed to be important in determining a course of treatment, including the decision whether to use their Factor VIII and/or Factor IX blood products.

PARAGRAPH NO. 86 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 86 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 86 of the Complaint.

87. As a direct and proximate result of Defendants' fraudulent concealment and suppression of material health and safety risks relating to their Factor VIII and Factor IX blood products and of Defendants' dangerous and irresponsible plasma collection practices, Plaintiff has suffered and will continue to suffer injury, harm and economic loss. As the direct, proximate and legal result of the Defendants' fraudulent concealment and suppression of material health and safety risks relating to their Factor VIII and Factor IX blood products and of Defendants' dangerous and irresponsible plasma collection practices, Plaintiff has been injured and has incurred damages, including but not limited to physical injuries to his person, medical expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and may incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

PARAGRAPH NO. 87 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 87 of the Complaint. Bayer is

without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 87 of the Complaint.

88. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 88 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 88 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 88 of the Complaint.

89. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

PARAGRAPH NO. 89 ANSWER: Bayer denies the allegations in Paragraph 89 of the Complaint.

90. Plaintiff is informed and believes that Defendants utilize retention policies that provide for scheduled destruction of documents and other items, which may result in the knowing, negligent, or inadvertent destruction of documents, data, and materials relevant and necessary to adjudication of this action, including, but not limited to, records identifying batch or lot numbers of Defendants' products shipped to particular treatment facilities, which may facilitate product tracing. This risk warrants an order from this Court that such evidence (including all documents, data compilations, and tangible things within the meaning of Rule 26 of the Federal Rules of Civil Procedure) be preserved and maintained for use in these proceedings.

PARAGRAPH NO. 90 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 90 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 90 of the Complaint.

Answer to Plaintiff's Breach of Implied Warranty Allegations

91. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

PARAGRAPH NO. 91 ANSWER: Bayer incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

92. Defendants' factor concentrate products were intentionally designed, manufactured, promoted, distributed and sold to be introduced into the human body.

PARAGRAPH NO. 92 ANSWER: Bayer admits that it processed and distributed Factor VIII or Factor IX for the treatment of hemophilia and that its Factor VIII and Factor IX concentrates were intended to be introduced into the body as part of a medical "service". Bayer denies that its factor concentrates were "products", "manufactured", or "sold". Except as admitted or denied above, to the extent matters set forth in Paragraph 92 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 92 of the Complaint.

93. Defendants breached the implied warranties of merchantability and fitness because Defendants' factor concentrate products cannot pass without objection in the trade, are

unsafe, are not merchantable, are unfit for their ordinary use when sold, and are not adequately packaged and labeled.

PARAGRAPH NO. 93 ANSWER: The allegations in Paragraph 93 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, and to the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 93 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 93 of the Complaint.

94. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 94 ANSWER: To the extent they are directed to Bayer and/or its predecessors, Bayer denies the allegations in Paragraph 94 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 94 of the Complaint.

Answer to Plaintiff's Negligence Allegations

95. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

PARAGRAPH NO. 95 ANSWER: Bayer incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

96. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiff, and knew or should have known that Plaintiff would use their Factor VIII and/or Factor IX blood products.

PARAGRAPH NO. 96 ANSWER: Bayer admits that it processed and distributed Factor VIII or Factor IX for the treatment of hemophilia. To the extent they are directed to Bayer and/or its predecessors, Bayer denies any remaining allegations in Paragraph 96 of the Complaint. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 96 of the Complaint.

97. Defendants owed Plaintiff duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

PARAGRAPH NO. 97 ANSWER: The allegations in Paragraph 97 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 97 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 97 of the Complaint.

98. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff. The following sub-paragraphs summarize Defendants' breaches of duties to Plaintiff and describe categories of acts or omissions constituting breaches of duties by Defendants. Each and/or any of these acts or omissions establishes an independent basis for Defendants' liability in negligence:

a. Failure to exercise reasonable care in producing Factor VIII and Factor IX blood products that were free of viruses, including the virus that causes Hepatitis C;

b. Failure to exercise reasonable care in assuring that only suitable plasma would be used in manufacturing their Factor VIII and Factor IX blood products;

c. Failure to exercise reasonable care in testing plasma used in manufacturing their Factor VIII and Factor IX blood products for viral contamination;

d. Failure to exercise reasonable care in recruiting and screening donors of plasma used in their manufacture of Factor VIII and Factor IX blood products;

e. Failure to reasonably employ anti-viral techniques, including solvent and/or detergent treatment, in the manufacture of their Factor VIII and Factor IX blood products;

f. Unreasonable overpromotion of their Factor VIII and Factor IX blood products;

g. Understating the relative value of hemophilia treatments that constituted alternatives to their Factor VIII and Factor IX blood products;

h. Failure to warn physicians, Plaintiff, his guardians and the hemophilia community of the dangers associated with their Factor VIII and Factor IX blood products and/or the viruses and foreign bodies contained within the plasma used in manufacturing their Factor VIII and Factor IX blood products;

i. Failure to exercise reasonable care by complying with federal regulations then applicable to plasma collection and the manufacture of Factor VIII and Factor IX blood products;

j. Failure to exercise reasonable care in disseminating information about their methods of manufacturing their Factor VIII and Factor IX blood products and the risks that were created by said methods; and

k. Failure to exercise reasonable care in recalling their Factor VIII and Factor IX blood products.

PARAGRAPH NO. 98 ANSWER: The allegations in Paragraph 98, including subparagraphs (a) through (k), of the Complaint set forth conclusions of law to which no

response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 98, including subparagraphs (a) through (k), of the Complaint to the extent that they are directed to Bayer and/or its predecessors. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 98 of the Complaint.

99. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiff and other people with hemophilia, would use and did use Defendants' Factor VIII and/or Factor IX products to the detriment of their health, safety and well-being.

PARAGRAPH NO. 99 ANSWER: To the extent matters set forth in Paragraph 99 are directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 99 of the Complaint.

100. As the direct, proximate and legal result of the Defendants' negligence, Plaintiff has been injured and has incurred damages, including but not limited to physical injuries to his person, medical expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and may incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

PARAGRAPH NO. 100 ANSWER: To the extent matters set forth in Paragraph 100 are directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 100 of the Complaint.

101. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 101 ANSWER: To the extent matters set forth in Paragraph 101 are directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 101 of the Complaint.

102. Defendants' conduct, as alleged above, was malicious, intentional and outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

PARAGRAPH NO. 102 ANSWER: To the extent matters set forth in Paragraph 102 are directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 102 of the Complaint.

Answer to Plaintiff's Negligence Per Se Allegations

103. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

PARAGRAPH NO. 103 ANSWER: Bayer incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

104. Defendants violated applicable federal statutes and regulations relating to prescription drugs. Plaintiff is a person whom these statutes and regulations were meant to protect.

PARAGRAPH NO. 104 ANSWER: The allegations in Paragraph 104 of the Complaint set forth conclusions of law to which no response is required. To the extent that a

response is required, Bayer states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care. To the extent the allegations in Paragraph 104 are intended to constitute allegations of a defect, wrongdoing or failure to exercise due care directed to Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 104 of the Complaint.

105. Defendants' violation of these statutes or regulations constitutes negligence per se.

PARAGRAPH NO. 105 ANSWER: The allegations in Paragraph 105 of the Complaint set forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations in Paragraph 105 of the Complaint.

106. Defendants' violation of these statutes or regulations was the direct, proximate and legal cause of Plaintiff's injuries and damages. As the direct and legal result of the Defendants' negligence, Plaintiff has been injured and has incurred damages, including but not limited to permanent physical injuries to his person, medical and hospital expenses in the past, past disability, past loss of use of the body, and past physical and mental pain and suffering; and will incur in the future medical and hospital expenses, permanent disability, loss of use of the body, physical and mental pain and suffering, and loss of the enjoyment of life.

PARAGRAPH NO. 106 ANSWER: Bayer denies that it violated any statutes or regulations and denies that Bayer was the cause of Plaintiff's alleged injuries or damages. Bayer states that Bayer at all times complied with all applicable statutes and regulations, acted within the then existing state of medical and scientific knowledge, and proceeded with due care.

To the extent matters set forth in Paragraph 106 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 106 of the Complaint.

107. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 107 ANSWER: Bayer denies that Plaintiff is entitled to any damages from Bayer. To the extent matters set forth in Paragraph 107 are intended to constitute allegations of a defect, wrongdoing or a failure to exercise due care directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 107 of the Complaint.

108. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

PARAGRAPH NO. 108 ANSWER: To the extent matters set forth in Paragraph 108 are directed at Bayer and/or its predecessors, Bayer denies them. Bayer is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 108 of the Complaint.

WHEREFORE, Bayer demands that the Court dismiss Plaintiff's claims with prejudice, enter judgment in favor of BAYER, and award Bayer such other relief as the Court deem just and appropriate.

Second Defense

109. Bayer asserts that the claims made in Plaintiff's Complaint are governed by the laws of the country or state (defined herein to include foreign and domestic states) in which Plaintiff currently resides and not the law of Illinois. In any event, if Plaintiff cannot recover in the jurisdiction in which s/he currently resides, comity requires that Plaintiff be denied recovery in this Court.

Third Defense

110. The Complaint does not contain sufficient facts to constitute a legally cognizable claim against Bayer and/or its predecessors, and all claims against Bayer should be dismissed for failure to state a claim upon which relief may be granted.

Fourth Defense

111. All or part of the claims for relief contained in Plaintiff's Complaint are barred by the applicable statute of limitations, repose or similar statutes, regulations or policies.

Fifth Defense

112. If Plaintiff sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were directly and proximately caused by the negligence or fault of parties other than Bayer, whether named or unnamed in Plaintiff's Complaint, over whom Bayer had no supervision or control and for whose actions and omissions Bayer has no legal responsibility. Plaintiff's recovery, if any, therefore should be apportioned in accordance with the applicable law.

Sixth Defense

113. Plaintiff's claim for relief is barred because Plaintiff, directly or through his/her physicians, assumed the risk and was fully cognizant of all circumstances surrounding the

utilization of any Factor VIII or Factor IX concentrates processed by Bayer and/or its predecessors.

Seventh Defense

114. The state of the medical and scientific knowledge, and the published literature and other materials reflecting the state of the medical art, at all times pertinent to this action, was such that Bayer and/or its predecessors neither knew nor could have known that its factor concentrates presented a foreseeable risk of harm to the Plaintiff based on normal and expected usage.

Eighth Defense

115. Bayer's and/or its predecessor's Factor VIII and Factor IX concentrates were processed and distributed in accordance with directives and consistent with the regulations of the United States FDA and other applicable regulatory authorities and, therefore, any claim by Plaintiff is barred by the doctrine of preemption.

Ninth Defense

116. Plaintiff's Complaint fails to state a claim upon which relief can be granted against Bayer because any Factor VIII and Factor IX concentrates distributed by Bayer and/or its predecessors were in accordance with the applicable state-of-the-art, the state of scientific knowledge and all applicable regulations of the FDA and other applicable regulatory authorities, and distributed pursuant to the approval of the FDA and other applicable regulatory authorities.

Tenth Defense

117. Any Factor VIII and Factor IX concentrates Bayer and/or its predecessors prepared or supplied were derived from human blood and constituted a service and, accordingly,

pursuant to applicable "blood shield statutes" and similar doctrines, Bayer is not liable under any theory of product liability.

Eleventh Defense

118. The claims of Plaintiff fail because Plaintiff has failed to take steps to mitigate damages, if any, and his/her recovery must be diminished accordingly.

Twelfth Defense

119. At all relevant times, Bayer's and/or its predecessor's Factor VIII or Factor IX concentrates were, under Federal law and the laws of the other relevant jurisdictions, only available from or on the order of a licensed physician, and persons other than Bayer, including Plaintiff's treating physicians and health care personnel and institutions, stood in the position of learned intermediary between Bayer and Plaintiff. The claims in the Complaint against Bayer accordingly are barred in whole or in part by the learned intermediary doctrine.

Thirteenth Defense

120. Plaintiff's claims are barred, in whole or in part, by laches, waiver and/or estoppel.

Fourteenth Defense

121. The Northern District of Illinois is an improper and/or inconvenient venue for this action because this venue imposes oppressiveness and vexation on Bayer out of all proportion to Plaintiff's convenience.

Fifteenth Defense

122. If Plaintiff sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper

handling, or other unforeseeable misuse of any Factor VIII and Factor IX concentrates Bayer and/or its predecessors prepared or supplied.

Sixteenth Defense

123. If Plaintiff sustained any injuries or damages as a result of the matters alleged, such damages and injuries, if any, were contributed to and caused by the negligence or other wrongful conduct of persons whose conduct is imputed by law to Plaintiff, constituting a bar to any recovery by Plaintiff or, in the alternative, recovery, if any obtained, should be reduced to the extent the negligence of such other persons or parties was a cause of the injuries and damages.

Seventeenth Defense

124. Plaintiff's claims are barred by the doctrine of *res judicata* and/or collateral estoppel.

Eighteenth Defense

125. Bayer specifically denies the existence of any implied warranties of merchantability and/or fitness. In the alternative, the warranty claims are barred by lack of privity and failure to provide reasonable and adequate notice of any breach of such warranties.

Nineteenth Defense

126. All factor concentrates prepared and provided by Bayer and/or its predecessors, including their labels and labeling, have been approved by the appropriate regulatory agencies pursuant to applicable statutes and regulations; approval and preparation of said factor concentrates was in compliance with all requirements pertaining to the preparation and/or distribution of such factor concentrates and was accomplished pursuant to acceptable standards of conduct.

Twentieth Defense

127. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Bayer's rights under the United States Constitution and any applicable State constitutions.

Twenty-First Defense

128. Plaintiff's Complaint fails to plead fraud with particularity as required by Rule 9(b), Federal Rules of Civil Procedure.

Twenty-Second Defense

129. Plaintiff cannot state a claim with regard to warnings and labeling for prescription biologicals because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

Twenty-Third Defense

130. This court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription biological labeling by the FDA.

Twenty-Fourth Defense

131. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

Twenty-Fifth Defense

132. Plaintiff did not detrimentally rely on any labeling, warnings or information concerning Factor VIII and Factor IX concentrates.

Twenty-Sixth Defense

133. Plaintiff's claims are preempted by previously filed litigation in the United States and abroad.

Twenty-Seventh Defense

134. Plaintiff's claims for punitive or exemplary damages are barred under any applicable State and/or federal law. Permitting recovery of punitive or exemplary damages in this case would contravene Bayer's constitutional rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and any applicable State constitutions.

Twenty-Eighth Defense

135. Because of the lack of clear standards, the imposition of punitive or exemplary damages against Bayer would be unconstitutionally vague and/or overbroad.

Twenty-Ninth Defense

136. With respect to Plaintiff's demand for punitive or exemplary damages, Bayer specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under the applicable law.

Thirtieth Defense

137. No act or omission of Bayer constituted intentional misconduct or gross negligence, nor was any act or omission of Bayer outrageous or with ill will, bad motive or reckless indifference to the interest of consumers, and Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages. Plaintiff's Complaint seeks damages in excess of those permitted by law. Bayer asserts any statutory or judicial

protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

Thirty-First Defense

138. Any award of punitive or exemplary damages against Bayer is barred to the extent that it is inconsistent with any applicable standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 134 L. Ed. 2d 809, 116 S. Ct. 1589 (1996), and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 123 S. Ct. 1513 (2003).

Thirty-Second Defense

139. To the extent that Plaintiff relies upon the doctrine of market share liability or alternative liability, Plaintiff fails to state a claim upon which relief may be granted.

Thirty-Third Defense

140. Plaintiff's Complaint fails to state a claim against Bayer upon which relief can be granted for several or joint and several liability.

Thirty-Fourth Defense

141. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

Thirty-Fifth Defense

142. Plaintiff's Complaint fails to state a cause of action for fraudulent omission, concealment, or "willful", "malicious" or "outrageous" conduct against Bayer for which relief may be granted.

Thirty-Sixth Defense

143. Fraudulent misrepresentations made, if any, were not relied on by Plaintiff.

Thirty-Seventh Defense

144. At all times, Bayer and/or its predecessors, and anyone for whom it was responsible, fulfilled every duty imposed upon them by law and, as such, can have no liability.

Thirty-Eighth Defense

145. Plaintiff's Complaint fails to state a claim upon which relief can be granted as to interest, costs and attorneys' fees.

Thirty-Ninth Defense

146. At all relevant times, Bayer's conduct was in compliance with applicable foreign regulations issued by the applicable foreign authorities, and Plaintiff's recovery against Bayer is therefore barred.

Fortieth Defense

147. Plaintiff's alleged injuries and damages, if any, were the result of an idiosyncratic reaction which Bayer could not reasonably foresee.

Forty-First Defense

148. The injuries and damages claimed by Plaintiff, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Bayer was not the proximate and/or competent producing cause of such alleged injuries and damages.

Forty-Second Defense

149. The alleged injuries of Plaintiff were the result of unavoidable circumstances, which could not have been prevented by anyone.

Forty-Third Defense

150. Plaintiff failed to give timely notice of his/her breach of warranty claims, if any, and therefore is precluded from recovery.

Forty-Fourth Defense

151. Plaintiff's claims are barred, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged with regulating biologics, including factor concentrates, and is specifically charged with determining the content of the warnings and labeling for biologics.

Forty-Fifth Defense

152. To the extent that Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, under federal law such claims are barred pursuant *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Forty-Sixth Defense

153. To the extent Plaintiff attempts to seek equitable relief, s/he is not entitled to such relief because s/he has an adequate remedy at law.

Forty-Seventh Defense

154. Some of Plaintiff's claims are barred in whole or in part by the First Amendment to the Constitution of the United States and/or the applicable constitution or equivalent legal document of any State whose laws might be deemed controlling in this case.

Forty-Eighth Defense

155. Plaintiff's injuries and losses, if any, were proximately caused by his/her own failure to use factor concentrate in a reasonably foreseeable and intended manner, or in a manner consistent with the therapy's labeling and their claims are therefore barred.

Forty-Ninth Defense

156. If it is determined that a risk is inherent in factor concentrates, then such risk is outweighed by the benefits of factor concentrates.

Fiftieth Defense

157. To the extent that Plaintiff relies on the doctrine of failure to warn, s/he has failed to state a claim upon which relief may be granted.

Fifty-First Defense

158. In collecting plasma and processing and distributing Factor VIII and Factor IX concentrate, Bayer has undertaken to supply the public with an apparently useful and desirable medical therapy. The public interest and the availability of such therapies, as well as the Restatement of Torts, precludes liability for any risks resulting from such activities which were unavoidable given the state of human knowledge at the time those activities were undertaken.

Fifty-Second Defense

159. Bayer reserves the right to make a written election of credit for settlements under applicable law. Bayer further demands that its fault and/or responsibility be compared to other parties and non-parties to this suit as provided by any governing statutory or common-law scheme of comparative fault, comparative responsibility and contribution.

Fifty-Third Defense

160. Plaintiff is not the real party in interest or lacks the capacity and/or standing to bring the claims asserted in the Complaint.

Fifty-Fourth Defense

161. Bayer adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Bayer's defenses pleaded in this Answer.

Fifty-Fifth Defense

162. Bayer has not knowingly or intentionally waived any applicable defenses, and asserts all defenses available under the law of the state in which Plaintiff resides. Bayer reserves the right to amend its answer and separate and additional defenses to conform to such facts as may be revealed in discovery or otherwise.

PRAYER FOR RELIEF

WHEREFORE, Defendant BAYER CORPORATION prays for judgment as follows:

1. That Plaintiff takes nothing by virtue of the Complaint;

2. That if Plaintiff is awarded damages, those damages be apportioned among all parties, persons and entities, and/or their agents, servants and employees whose conduct contributed to the claimed injuries and damages;

3. For Attorneys' fees and costs of suit incurred herein; and

4. For such other and further relief as the Court may deem just and proper.

Dated: August 15, 2008

Respectfully submitted,

By: /s/ Geoffrey Smith

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DEMAND FOR JURY TRIAL

Defendant Bayer Corporation demands a trial by jury on all issues stated.

Dated: August 15, 2008

Respectfully submitted,

BY: /s/ Geoffrey Smith

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CERTIFICATE OF INTERESTED ENTITIES OR PARTIES

Pursuant to Civil L.R. 3.2, the undersigned certifies that the following listed persons, associations of persons, firms, partnerships, corporations (including parent corporations) or other entities (i) have a financial interest in the subject matter in controversy or in a party to the proceeding, or (ii) have a non-financial interest in that subject matter or in a party that could be substantially affected by the outcome of this proceeding.

Name	Type of Interest
Bayer Corporation 100 Bayer Road Pittsburgh, Pennsylvania 15205-9741	Party
Bayer AG 51368 Leverkusen Germany	Parent Corporation

Dated: August 15, 2008

Respectfully submitted,

BY: /s/ Geoffrey Smith

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CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of August 2008, I filed the foregoing pursuant to the procedures for electronic filing of documents for the United States District Court for the Northern District of Illinois and that I also deposited a copy of same in the United States mail postage prepaid bearing first class addressed as below:

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